K110587

Bayer HealthCare

MAR 2 8 2012

510(k) SUMMARY

Summary of 510(k) safety and effectiveness in accordance with the requirements of 21 CFR 807.92.

Submitter Information	
Name	Bayer Healthcare
Address	555 White Plains Road Tarrytown, NY 10591
Phone number	(914) 366-1800
Fax number	(914) 366-1899
Establishment Registration Number	3003962513
Name of contact person	Chuck Ryan
Date prepared	March 27, 2012
Name of device	
Trade or proprietary name	CONTOUR® LINK
Common or usual name	Wireless Blood Glucose Monitoring System
Classification name	Glucose Test System
Classification panel	Clinical Chemistry and Clinical Toxicology
Regulation	21 CFR 862.1345
Product Code(s)	LFR (Glucose Dehydrogenase, Glucose), NBW (System, Test, Blood Glucose, Over The Counter)
Legally marketed device(s) to which equivalence is claimed	CONTOUR Blood Glucose Meter (K062058) OneTouch UltraLink Blood Glucose Meter (K073231)
Reason for 510(k) submission	Addition of RF wireless transmission capability
Device description	The CONTOUR LINK Wireless Blood Glucose Monitoring System features the CONTOUR LINK Wireless Blood Glucose Monitor and the currently marketed CONTOUR Blood Glucose Test Strips, among other components (e.g., lancing device, lancets and control solution)

Intended use of the device	See Indications for Use below
Indications for use	The CONTOUR® LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR® LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip only. CONTOUR® test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL. The CONTOUR® LINK Wireless Blood Glucose Monitoring System is intended to be used to transmit glucose values to Medtronic MiniMed Paradigm Insulin Pumps or Medtronic MiniMed Paradigm REAL-Time Revel Insulin Pumps through use of radio frequency communication. The CONTOUR® LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Summary of the Technological Characteristics of the New Device Compared to Predicate 1

SIMILARITIES to Predicate 1

Characteristic	New Device Bayer's CONTOUR LINK meter	Predicate 1 Bayer's CONTOUR meter K062058
Detection Technology	Amperometric measurement of blood glucose	same
Reference method	Plasma equivalent	same
Test strip	CONTOUR test strip	same

Test Strip enzyme	Glucose Dehydrogenase FAD	same
Calibration/Coding	No coding needed	same
Accuracy	Meets ISO 15197 requirements	same
Reaction time	5 seconds	same
DIFFERENCES from Predicate 1		
RF Communication Protocol	Transmits glucose values to compatible MiniMed Paradigm and Guardian REAL Time devices.	No RF capability
Alternative site testing	Fingertip only	Fingertip, palm or forearm
Measurement range	20-600 mg/dL	10-600 mg/dL
Sample type	Capillary whole blood samples only. Not for use on neonates.	Capillary, venous, and arterial whole blood samples and neonatal blood samples
Hct range	20-65%	0-70%
Summary of the Technological Characteristics of the New Device Compared to Predicate 2		
SIMILARITIES to Predicate 2		
Characteristic	**New Device Bayer's CONTOUR LINK meter**	**Predicate 2 LifeScan OneTouch UltraLink meter K073231**
Detection Technology	Amperometric measurement of blood glucose	same

Reference method	Plasma equivalent	same
Accuracy	Meets ISO 15197 requirements	same
Sample type	Capillary whole blood samples only. Not for use on neonates.	same
Reaction time	5 seconds	same
Measurement range	20-600 mg/dL	same
RF Communication Protocol	Transmits glucose values to compatible Medtronic MiniMed devices.	same
DIFFERENCES from Predicate 2		
Test Strip	CONTOUR test strip	OneTouch Ultra test strip
Test Strip enzyme	Glucose Dehydrogenase FAD	Glucose Oxidase
Alternative site testing	Fingertip only	Fingertip, palm or forearm
Calibration/Coding	No coding needed	Manual coding required
Hct range	20-65%	30-55%
PERFORMANCE DATA		
SUMMARY OF NON-CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE		
Performance Test Summary-New Device		
Characteristic	Results Summary	

Precision	**Repeatability (ISO 15197 Section 7.2.2)** **Reference: 510(k) submission, Section 018-4** **Protocol:** Venous blood was tested at five glucose concentration ranges: 30 – 50, 51 – 110, 111 – 150, 151 – 250 and 251 – 400mg/dL. One lot of test strips was tested on 10 meters with 10 replicates per meter (n=100). **Acceptance criteria:** No ISO acceptance criteria stated. Internal acceptance criteria: Repeatability test must perform within the established accuracy requirements. (C_{pk} values > 1.0 when compared to established accuracy requirements of ± 20% or ± 15mg/dL.). **Results:** C_{pk} values are greater than 1.0 when compared to established accuracy requirements of ± 20% or ± 15mg/dL. Mean, SD and %CV were as follows:

Mean, mg/dL	SD,mg/dL	CV%
41.8	1.26	3.02%
78.1	1.99	2.55%
125.7	2.67	2.12%
198.0	4.32	2.18%
312.3	5.01	1.60%

Intermediate Precision (ISO 15197 Section 7.2.3)
Reference: 510(k) submission, Section 018-4

Protocol: Three levels of control solutions (Low, Normal and High) were tested on 10 meters over the course of 10 days. One measurement was taken per meter per lot per control solution per day.
Acceptance criteria: Cp value for 10 days> 1.0 when compared to established limits of + 11% or +5mg/dL.
Results: Cp values are over 1.0 when compared to established limits of + 11% or + 5mg/dL.

Mean, SD and %CV were as follows:

Control Level	Mean, mg/dL	SD,mg/dL	CV%
Low	38.9	0.55	1.41
Normal	121.7	1.26	1.04
High	354.9	4.49	1.26

<table>
<tr><td>Accuracy</td><td>System Accuracy Evaluation (ISO 15197 Section 7.3)
Reference: 510(k) submission, Section 018-5

Protocol: Fresh capillary blood was collected in the glucose range distribution specified by ISO 15197 Section 7.3. One hundred blood samples were tested using each of two CONTOUR test strip lots on two CONTOUR LINK meters for a total of 400 readings. Samples were also tested in parallel on a YSI 2300 STAT PLUS glucose analyzer.

Acceptance Criteria: A minimum of 95 % of the individual glucose results shall fall within ± 15 mg/dL of the results obtained on the YSI analyzer at glucose concentrations < 75 mg/dL, and within ± 20 % at glucose concentrations ≥75 mg/dL.

Results: 98.7 % of the individual glucose results fell within ± 15 mg/dL of the results obtained on the YSI analyzer at glucose concentrations < 75 mg/dL. 98.5% fell within ± 20 % at glucose concentrations ≥75 mg/dL.</td></tr>
<tr><td>Linearity/assay reportable range</td><td>Established in predicate submission (k062058).

Reference: 510(k) submission, Section 018-7
Two studies were conducted to establish the linearity of the CONTOUR system throughout the entire reportable range of 10 to 600 mg/dL. In one study, blood with a hematocrit level of 40% was adjusted to plasma glucose concentrations of 20, 30, 40, 50, and 60 mg/dL and tested with three CONTOUR lots, 24 sensors per lot. All results fell within ±10mg/dL of the YSI reference value, satisfying the acceptance criteria.

<table>
<tr><th>Reference Level, mg/dL</th><th>Mean, mg/dL</th><th>Bias, mg/dL</th><th>CV, %</th></tr>
<tr><td>29.5</td><td>25.5</td><td>-4.0</td><td>3.2</td></tr>
<tr><td>40.6</td><td>35.3</td><td>-5.3</td><td>4.2</td></tr>
<tr><td>50.6</td><td>45.5</td><td>-5.0</td><td>2.1</td></tr>
<tr><td>60.3</td><td>54.4</td><td>-5.9</td><td>2.5</td></tr>
</table>

Reference: 510(k) submission, Section 018-6
An additional study using three pilot production sensor lots tested sensor response across eight plasma glucose concentrations.</td></tr>
</table>

<table>
<tr><td></td><td>Eight meters were used, with three sensors per lot tested on each. All results fell within ±20% at glucose level of 75 mg/dL and above, and within ±15 mg/dL at glucose level below 75 mg/dL. This met the acceptance criteria.
<table>
<tr><th>Reference Level, mg/dL</th><th>Mean, mg/dL</th><th>Bias</th><th>CV, %</th></tr>
<tr><td>26.4</td><td>25.8</td><td>-0.5 mg/dL</td><td>3.5</td></tr>
<tr><td>51.1</td><td>47.2</td><td>-3.9 mg/dL</td><td>2.2</td></tr>
<tr><td>77.6</td><td>74.8</td><td>-3.5%</td><td>2.1</td></tr>
<tr><td>118.1</td><td>115.2</td><td>-2.5%</td><td>2.7</td></tr>
<tr><td>195.8</td><td>194.7</td><td>-0.5%</td><td>2.3</td></tr>
<tr><td>300.0</td><td>304.9</td><td>1.6%</td><td>2.3</td></tr>
<tr><td>394.5</td><td>398.3</td><td>1.0%</td><td>1.5</td></tr>
<tr><td>551.0</td><td>530.5</td><td>-3.7%</td><td>1.7</td></tr>
</table></td></tr>
<tr><td>Traceability</td><td>The Yellow Springs Instruments Stat Plus 2300 analyzer (YSI) is traceable to the hexokinase method developed collaboratively by the FDA, CDC, NIST and AACC. The hexokinase method is incorporated in a Bayer procedure that utilizes NIST Standard Reference Material 917, dry D-glucose. Glucose serum controls from an outside supplier were characterized by Bayer using the hexokinase method as a reference. For each day that Bayer's YSI instruments were used as the reference method, the serum controls were analyzed to ensure that the instruments were in control.</td></tr>
<tr><td>Detection limit</td><td>Established in predicate submission (k062058) as 10-600 mg/dL; stated in CONTOUR LINK specifications as 20-600 mg/dL due to absence of neonatal claim.

Reference: 510(k) submission, Section 018-7
The low glucose concentration testing conducted as part of the Linearity/Assay Reportable Range above confirmed detection limit. In addition, three production lots of CONTOUR sensors were tested with whole blood samples manipulated to have glucose concentrations of 5, 900, 1200, 1500 and 1800 mg/dL, 24 sensors per samples. All readings of the 5 mg/dL samples displayed "Lo" and all readings of 900 mg/dL or greater displayed "Hi".</td></tr>
<tr><td>Analytical</td><td>Reference: 510(k) submission, Section 018-8; Response to</td></tr>
</table>

<table>
<tr><td>specificity</td><td>First Additional Information Request
The interference effects of several substances were evaluated per the table below.
<table>
<tr><th>Compound</th><th>Added Amount</th><th>Signal Change Criterion at 80 and 300 mg/dL glucose</th><th>Result</th></tr>
<tr><td>Bilirubin</td><td>>20 mg/dL</td><td>≤10%</td><td>Passed</td></tr>
<tr><td>Acetaminophen</td><td>>22 mg/dL</td><td>≤10%</td><td>Passed</td></tr>
<tr><td>Uric Acid</td><td>>18 mg/dL</td><td>≤10%</td><td>Passed</td></tr>
<tr><td>Ascorbic Acid</td><td>>30 mg/dL</td><td>≤10%</td><td>Passed</td></tr>
<tr><td>Maltose</td><td>>200 mg/dL</td><td>≤7%</td><td>Passed</td></tr>
<tr><td>Galactose</td><td>>200 mg/dL</td><td>≤7%</td><td>Passed</td></tr>
<tr><td>Xylose</td><td colspan="3">Interferes with test</td></tr>
</table></td></tr>
<tr><td>Assay cut-off</td><td>Not applicable</td></tr>
<tr><td colspan="2">COMPARATIVE PERFORMANCE INFORMATION SUMMARY</td></tr>
<tr><td>Method comparison with predicate device (k062058)</td><td>Reference: 510(k) submission, Section 018-3

Protocol: The CONTOUR and CONTOUR LINK meters were tested in a comprehensive fingerstick study using fresh capillary blood samples. In this study, the RF function of the CONTOUR LINK was left on to simulate real-world usage.

Materials and Method

Samples from 111 subjects were collected by fingerstick and tested using two lots of CONTOUR sensors. Four CONTOUR meters were used, with disinfection between each subject. Plasma samples were tested in duplicate on the YSI reference method, with the average value used for the comparison. Hematocrit values also were measured. All measurements were performed at 23°C ± 5°C.

In most cases, samples were tested fresh from the finger without any modification. However, samples at very low and very high glucose concentrations were created by either glycolyzing a specimen to lower the glucose concentration or supplementing a specimen with a concentrated glucose solution to increase the glucose level.

Acceptance Criteria:</td></tr>
</table>

	A proportionally weighted Deming regression of the CONTOUR sensor data was used to calculate slope, intercept, and the 95% confidence interval around the slope and intercept estimates shall include a 1.0 and 0.0, respectively. **Results:** A total of 444 paired readings were collected. The plasma glucose range was 23 to 468 mg/dL, and the hematocrit range was 25% to 51.5%. A proportionally weighted Deming regression model was used to calculate slope and intercept estimates. The system performance meets the acceptance criteria. Slope: 0.989, confidence interval = 0.989 to 1.008 Intercept: 0.49, confidence interval = -0.4 to 1.38 mg/dL
Linearity/assay reportable range – comparison with predicate device (k062058)	**Reference: 510(k) submission, Section 018-2** **Protocol:** Pooled fresh venous blood at plasma glucose concentrations of approximately 10, 45, 67, 134, 336, and 600 mg/dL were tested on eight CONTOUR LINK meters and eight CONTOUR meters with one lot of test strips. Each sample was tested three times on each meter, and a total of 24 readings were collected per system. **Acceptance criteria:** • 95% confidence interval width for the percent difference between CONTOUR LINK mean and CONTOUR mean is within ± 4% (± 3 mg/dL if glucose <75mg/dL) and includes ±1% (or ±0.75mg/dL). • Imprecision of the CONTOUR® LINK system is not significantly larger ($\alpha = 0.05$) than imprecision of the 5-second CONTOUR system or Cpk values are greater than 1.33. **Results:** Bias of the CONTOUR LINK system is not significantly larger than bias of the predicate CONTOUR system (k062058)
SUMMARY OF CLINICAL TESTS CONDUCTED FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE AND/OR OF CLINICAL INFORMATION	
Clinical study	**Reference: 510(k) submission, Section 020,** **Protocol:** The subject pool included 77 adults aged 20 through 85, each diagnosed with diabetes. The ability to follow instructions

	for use for self-testing, and the resulting accuracy of results, were assessed. **Results:** Statistical analysis of the data indicates that the probability exceeds 95% that a randomly selected person will successfully perform any of the tasks required for successful execution of the blood glucose testing procedure. The accuracy study component of the protocol demonstrated that 95.5% of self-test results and 99.4% of HCP-test results satisfy ISO 15197 accuracy specifications (at least 95% of results must be within ±15 mg/dL at <75 mg/dL and ±20% at >75 mg/dL). All control solution test performed by subjects (77) generated in-range glucose values, and all were marked as controls by the meters. **Reference: Predicate 510(k) K062058** **Protocol:** The subject device is equivalent to the predicate CONTOUR® device with RF transmission capability added. The subject pool included 109 adults aged 20 through 75, each diagnosed with diabetes. The ability to follow instructions for use for self-testing, and the resulting accuracy of results, were assessed. **Results:** Ninety-nine percent of the subjects either did not require any assistance or required answers to questions in an interaction that was comparable to a Customer Service call. Analytical accuracy of the subjects' self-testing was statistically indistinguishable from the laboratory glucose method. More than 96% were within the limits of ±15 mg/dL or ±20% of the laboratory glucose method, thus meeting the established performance criteria.
CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL DATA	
The performance of the CONTOUR® LINK Blood Glucose Monitoring System is equivalent to the performance of the previously cleared CONTOUR® Blood Glucose Monitoring System (k062058).	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bayer HealthCare LLC, Diabetes Care
c/o Charles Ryan
777 Old Saw Mill River Road
Tarrytown, NY 10591

MAR 28 2012

Re: k110587
Trade Name: CONTOUR® Link Wireless Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Glucose Test System
Regulatory Class: Class II
Product Codes: LFR, NBW
Dated: March 27, 2012
Received: March 28, 2012

Dear Mr. Ryan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number K110587:

Device Name: CONTOUR® LINK Wireless Blood Glucose Monitoring System

Indications for Use:

The CONTOUR® LINK Wireless Blood Glucose Monitoring System is an over the counter (OTC) device utilized by persons with diabetes in home settings for the measurement of glucose in whole blood, and is for single-patient use only and should not be shared. The CONTOUR® LINK Wireless Blood Glucose Monitoring System is indicated for use with fresh capillary whole blood samples drawn from the fingertip only.

CONTOUR® test strips are intended for self-testing by persons with diabetes for the quantitative measurement of glucose in whole blood samples from 20 to 600 mg/dL.

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The CONTOUR® LINK Wireless Blood Glucose Monitoring System is not intended for the diagnosis of or screening for diabetes mellitus and is not intended for use on neonates.

Prescription Use X	And/Or	Over the Counter Use X
(21 CFR Part 801 Subpart D)		(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110587